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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,796	01/23/2002	Emmanuel C. Opara	5405.223IPDV	4935
20792	7590	12/04/2003	EXAMINER	
MYERS BIGEL SIBLEY & SAJOVEC			NAFF, DAVID M	
PO BOX 37428			ART UNIT	
RALEIGH, NC 27627			PAPER NUMBER	

1651

DATE MAILED: 12/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/054,796	<b>Applicant(s)</b> OPARA, EMMANUEL C.	
	<b>Examiner</b> David M. Naff	<b>Art Unit</b> 1651	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 6-13, 77 and 84-86.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 6-13, 77 and 84-86 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-13, 77 and 84-86 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

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The amendment of 9/22/03 added new claims 85 and 86.

Claims examined on the merits are 6-13, 77 and 84-86 which are all claims in the application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 103***

Claims 6-13, 77 and 84-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brothers (5,821,121) (249 on 1449) in view of Brockbank (5,071,741) (50 on 1449) or Hamaguchi et al (272 on 1449) or Garfinkel et al (266 on 1449) each taken with Janjic et al (274 on 1449) or Littman et al (269 on 1449) or Garfindel et al (265 on 1449).

The claims are drawn to a microencapsulated islet cell product containing microcapsules containing pancreatic islet cells wherein the cells exhibit a weight gain of not more than 10 percent over a period of one month in a physiological saline solution at 37 degrees Celsius and exhibiting at least 150 percent basal insulin secretion in response to 16.7 millimolar glucose challenge in Krebs-Ringer physiological solution at pH 7.4 after the period of one month. Claims 85 and 86 require the encapsulated cells to be produced by incubating the microcapsules with a physiologically acceptable salt.

Brothers discloses culturing pancreatic islet cells in a medium containing glutathione (antioxidant) (col 42, line 16;

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col 49, line 45; and col 51, line 12). The cultured cells may be encapsulated for implanting (col 18, lines 31-41).

Brockbank, Hamaguchi et al and Garfinkel et al (document 266) disclose microencapsulation of pancreatic islets for transplantation.

Janjic et al, Littman et al and Garfindel et al (document 265) disclose enhancing insulin secretion of pancreatic islets by treating the islets with glutathione which functions as an antioxidant.

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It would have been obvious to carry out the encapsulation of pancreatic islet cells as suggested by Brothers by microencapsulating the cells to obtain the function of microencapsulating the pancreatic islets for transplantation as taught by Brockbank, Hamaguchi et al or Garfinkel et al (document 266) when microencapsulating pancreatic islets for transplantation. Janjic et al, Littman et al or Garfindel et al (document 265) would have suggested that glutathione in the medium of Brothers will function to enhance insulin secretion by the pancreatic islets. The resulting cultured microencapsulated cells would have inherently had a weight gain and basal insulin secretion as presently claimed. The medium of Brothers contains salts (column 49, line 29), and after encapsulating it would have been obvious to culture the islet cells in this medium. The salts would have inherently increased durability of the microcapsules.

***Response to Arguments***

Applicant's arguments filed 9/22/03 have been fully considered but they are not persuasive.

Applicant urges that the microencapsulated cell product of the claims is produced by using a physiologically acceptable salt. However, only claims 85 and 86 require the salt. As to these claims, Brothers discloses culturing with a medium containing salt, and it would have been obvious to culture the microencapsulated islets in this medium. The fact that Brothers

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may not have realized the claimed result of using the salt does not make the use of the salt unobvious. Moreover, it does not appear that using any salt in any amount will result in a significant increase in strength.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M.

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Naff whose telephone number is 703-308-0520. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in black ink, appearing to read 'David M. Naff', with a stylized flourish at the end.

David M. Naff  
Primary Examiner  
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